Message

From: Messina, Edward [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=95521FBF4E34496A879E364FAF7E5AA8-MESSINA, EDWARD]
Sent: 7/20/2018 7:22:58 PM
To: Vizard, Elizabeth [Vizard.Elizabeth@epa.gov]
Subject: RE: Importance of the GLP Audit and Inspection Program- Q from OECA on GLP inhibiting registrations

Thanks. Can you send me the new version once you incorporate so I can let my IO know that we addressed their concerns that the presentation represent the need for this program?

Ed Messina
Acting Deputy Office Director (Programs)
Office of Pesticide Programs
U.S. EPA
(703) 347-0209

From: Vizard, Elizabeth
Sent: Friday, July 20, 2018 2:00 PM
To: Messina, Edward <Messina.Edward@epa.gov>
Subject: RE: Importance of the GLP Audit and Inspection Program- Q from OECA on GLP inhibiting registrations

Thanks for the info. It is helpful and I'm going to add some of it to our slides for Susan. FYI, it is Craven Labs, not Kraven.

https://pubs.acs.org/subscribe/archive/tcaw/10/i11/html/11regs.html here's a good summary

The first major case of lab fraud to occur after the establishment of GLPs began in 1990 and involved Craven Labs, a commercial pesticide residue chemistry laboratory. An employee in Craven's Quality Assurance unit notified a corporate sponsor of fraudulent practices in a nationwide pesticide residue-testing program. This allegation was promptly reported to the EPA and triggered a two-year investigation that resulted in the 1992 criminal indictment of the company's president and three employees. The charges ranged from mail fraud to making false statements and concealing material facts to obstructing federal agency proceedings.

The criminal investigation of Craven Labs involved the Department of Justice's Environmental Crimes Division, the U.S. Attorney's office in Texas, the EPA's Criminal Investigation Division, and the EPA's Office of Prevention, Pesticides, and Toxic Substances. The relevant employees of every company that had conducted analyses at Craven Labs were extensively interrogated to determine whether or not they had colluded with the lab in generating false data. (In fact, no company was found to have conspired with the lab.) Most, if not all, current and prior employees of the lab were also interrogated. The investigation uncovered widespread data manipulation that began at least as early as 1980 and involved numerous pesticides.

The eventual indictment accused Craven Labs of secretly using a variety of "tricks" to falsify pesticide residue tests; the president and owner of the lab was accused of teaching the tricks to the employees. Specifically, the data manipulations included "overspiking" (i.e., varying sample injection volumes), dialing peaks using the zero control knob, diluting or concentrating standards, using methodologies that differed significantly from contracted methods, and keeping two sets of laboratory notebooks—one set containing the actual raw data and a second set containing falsified

data shown only to the sponsor and the EPA. Before the trial even started, 11 employees agreed to plead guilty to various felony and misdemeanor counts and cooperate with federal investigators.

Elizabeth Vizard, Chief
Pesticide, Waste & Toxics Branch
Monitoring, Assistance & Media Programs Division
Office of Compliance
202-564-5940

From: Messina, Edward
Sent: Friday, July 20, 2018 10:20 AM
To: Vizard, Elizabeth <Vizard.Elizabeth@epa.gov>
Subject: RE: Importance of the GLP Audit and Inspection Program- Q from OECA on GLP inhibiting registrations

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Ed Messina
Acting Deputy Office Director (Programs)
Office of Pesticide Programs
U.S. EPA
(703) 347-0209

From: Vizard, Elizabeth
Sent: Thursday, July 19, 2018 10:10 PM
To: Messina, Edward <Messina.Edward@epa.gov>
Subject: Re: Importance of the GLP Audit and Inspection Program- Q from OECA on GLP inhibiting registrations

FYI I reached out to Royan and Greg. I explained how we are very familiar with Ray's talking points. I offered to WCED that Martha and I can most likely answer whatever questions they have about the GLP program including how we

collaborate with OPP. I would prefer we loop in OPP as necessary if there's something we can't answer. Let me know if you will inform Jackie that FEAD can stand down for the moment or if you prefer I do it.

Elizabeth Vizard, Chief
Pesticides, Waste & Toxics Branch | Monitoring, Assistance & Media Programs Division | Office of Compliance
202-564-5940

On Jul 19, 2018, at 5:00 PM, Messina, Edward <Messina.Edward@epa.gov> wrote:

fyi

Ed Messina
Acting Deputy Office Director (Programs)
Office of Pesticide Programs
U.S. EPA
(703) 347-0209

From: Mosby, Jackie
Sent: Thursday, July 19, 2018 4:38 PM
To: Keigwin, Richard <Keigwin.Richard@epa.gov>; Messina, Edward <Messina.Edward@epa.gov>
Cc: Hopkins, Yvette <Hopkins.Yvette@epa.gov>; Wire, Cindy <Wire.Cindy@epa.gov>
Subject: FW: Importance of the GLP Audit and Inspection Program- Q from OECA on GLP inhibiting registrations

Rick, Yvette was asked by OECA to weigh in on CLA's assertion, and she was going to reach out to the regulatory divisions. Since you were copied on this, please let me know how you want to address CLA's email. If you want, FEAD is available to coordinate a response. Thanks, Jackie

Jacqueline E. Mosby, MPH
Director, Field & External Affairs Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
Phone: 703-308-2226, Cell: 202-999-9784, Fax: 703-305-6244
1200 Pennsylvania Avenue, N.W.
Mailstop: 7506P
Washington, DC 20460
Mosby.jackie@epa.gov

From: Hopkins, Yvette
Sent: Thursday, July 19, 2018 4:22 PM
To: Mosby, Jackie <Mosby.Jackie@epa.gov>; Herndon, George <Herndon.George@epa.gov>
Cc: Wire, Cindy <Wire.Cindy@epa.gov>; Wormell, Lance <Wormell.Lance@epa.gov>
Subject: FW: Importance of the GLP Audit and Inspection Program- Q from OECA on GLP inhibiting registrations

Jackie,

Royan asked me if OPP agrees with the email attached below in which CLA asserts the lack of GLP resources are affecting OPP's ability to grant registrations, among other things.

I told Royan I would send it to each regulatory division, but that was before I read the email and saw Rick and Ed were copied on the letter. Could you ask about how senior management would like to handle the response.
Yvette

From: Teter, Royan
Sent: Thursday, July 19, 2018 3:01 PM
To: Hopkins, Yvette <Hopkins.Yvette@epa.gov>
Subject: FW: Importance of the GLP Audit and Inspection Program

From: Sullivan, Greg
Sent: Thursday, July 19, 2018 1:04 PM
To: Teter, Royan <Teter.Royan@epa.gov>
Cc: Werner, Jacqueline <Werner.Jacqueline@epa.gov>
Subject: FW: Importance of the GLP Audit and Inspection Program

From: Bodine, Susan
Sent: Thursday, July 19, 2018 12:07 PM
To: Kelley, Rosemarie <Kelley.Rosemarie@epa.gov>; Sullivan, Greg <Sullivan.Greg@epa.gov>
Cc: Starfield, Lawrence <Starfield.Lawrence@epa.gov>; Traylor, Patrick <traylor.patrick@epa.gov>
Subject: FW: Importance of the GLP Audit and Inspection Program

From: Ray McAllister [mailto:RMcAllister@croplifeamerica.org]
Sent: Thursday, July 19, 2018 9:49 AM
To: Bodine, Susan <bodine.susan@epa.gov>
Cc: Starfield, Lawrence <Starfield.Lawrence@epa.gov>; Morris, Jeff <Morris.Jeff@epa.gov>; Wise, Louise <Wise.Louise@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>; Messina, Edward <Messina.Edward@epa.gov>; Letendre, Daisy <letendre.daisy@epa.gov>; Sharpe, Kristinn <Sharpe.Kristinn@epa.gov>; janet collins <jcollins@croplifeamerica.org>; Jay Vroom <JVroom@croplifeamerica.org>; Allison Jones (allisonjones@naicc.org) <allisonjones@naicc.org>
Subject: Importance of the GLP Audit and Inspection Program

Ms. Bodine:

On behalf of Crop Life America (CLA) and the National Association of Independent Crop Consultants (NAICC), we want to follow up the CLA visit with you on May 10 with more detail on the importance of the Good Laboratory Practice (GLP) Audit and Inspection program to the crop protection industry. We would welcome the opportunity to continue this conversation. I am taking the liberty of copying other EPA leaders with a stake in this program.

- We are concerned about a loss of vision within the management at the Environmental Protection Agency (EPA) regarding what the GLP program should do and be and accomplish.
- The GLP inspection and audit program is being starved of resources and personnel. In 1994, when the program was under the Office of Prevention, Pesticides, and Toxic Substances

(OPPTS), there were 19 inspectors, 6 support staff, and a contractor supporting the GLP program. Currently in the Office of Enforcement and Compliance Assurance (OECA) there are 4 inspectors and no support staff.

- A reasonable frequency of audit and inspection of the individual labs and facilities is necessary to assure EPA of the quality and integrity of the data supporting pesticide product registrations, as required by law, regulation, and international agreement.
- There are some 1400 laboratories, facilities, and field sites in the US participating in GLP research on pesticides. With current staffing of the audit and inspection program, keeping up with that number of facilities seems like an impossible task.
- By comparison, the burden of other GLP audit and inspection programs is more balanced, for example: US-FDA (300 labs, 75 inspectors); Canada (40 labs, 23 inspectors); UK (100 labs, 8 inspectors); Germany (160 labs, 53 inspectors). Many of these inspectors in other programs are part time.
- If inspections are not conducted with sufficient frequency, registrants may feel obligated to take their research to foreign contract research organizations (CROs), leading to loss of business for US laboratories.
- The US is obligated as a member of the Organization for Economic Cooperation and Development (OECD) to comply with requirements of formal OECD Decisions regarding GLP and audits and inspections. This has a direct bearing on the ability of US industry to operate internationally. Among other things, these requirements cover:
    - The nature and frequency of audits and inspections;
    - Providing statements of such audits and inspections to foreign governments in a timely manner.
- Historically, US has had a preeminent role in the development and management of the GLP and Mutual Acceptance of Data (MAD) programs under OECD. In recent years, EPA participation in the OECD GLP Committee and other international forums has been curtailed, resulting in loss of leadership, where the US should be in the forefront. The US should maintain active engagement in moulding and shaping the future direction of MAD.
- Because the EPA does <u>not</u> issue compliance certificates to GLP facilities, the inspection closure letters from EPA are vital in the registration submission process to many other countries, to assure studies have been conducted in a GLP-compliant facility. Lack of the closure letter creates a significant barrier to acceptance of US studies by other countries.
- Registrants experience delays in registrations when they have to obtain a closure letter from the laboratory to send to the monitoring authority in the foreign government. The current practice is to obtain the closure letter in advance to include with the study report in the registration application, and not wait for the monitoring authority to make a request.
- New CROs have a hard time breaking into the business, because of lack of inspections and lack of the ability to be inspected.
- The industry – both registrants and CROs – have a great deal of confidence in and respect for Francis Liem who has led the audit and inspection effort for many years. The Agency must maintain this level of experience and expertise.
- Interaction of audit and inspection staff with industry has been curtailed. We depend on frequent interaction with them in meetings and conferences to keep up to date on the latest developments in GLP.
- The prospect of additional funding authorized by the Pesticide Registration Improvement Act (PRIA) to bolster the GLP program is heartening. It is the clear intent of PRIA legislation that this additional funding supplement, and not replace, current funding from appropriations. It is essential that the new funds set aside for this purpose be spent exclusively on the GLP program.
- In 2016 there was serious consideration of moving the audit and inspection program to the Office of Chemical Safety and Pollution Prevention (OCSPP). We felt then and still feel now that this would be a very positive step for the program.
    - The GLP program began in OPPTS {now known as OCSPP), and was located there until the mid 1990s.

- The principle purpose of EPA's GLP program is to support the registration decisions made by the Office of Pesticide Programs (OPP) within OCSPP.
- With such an organizational change, the GLP program could be more responsive to the audit and inspection needs of OPP for specific studies and facilities.
- Administration of funds from product maintenance fees under PRIA for the GLP program would be simpler and more straightforward in OCSPP, which administers all other PRIA funds.
- The GLP program does not audit or inspect research performed by OPP, so the organizational connection would not represent a conflict of interest.
- OCSPP can maintain the appropriate organizational structure to assure independence of the GLP program.

- A robust GLP program in full compliance with the OECD MAD requirements demonstrates to all stakeholders the integrity of industry-supported and generated data that underpin pesticide registrations in the US and around the world. The EPA has a significant responsibility to vigorously defend its Pesticide Programs, and the GLP program should contribute in that regard.

Ray S. McAllister, Ph.D.
Senior Director, Regulatory Policy
CropLife America
202-872-3874 (office)
202-577-6657 (mobile)
ray@croplife.us

Allison Jones
Executive Vice President
National Alliance of Independent Crop Consultants (NAICC)
901.861.0511
AllisonJones@NAICC.org
www.NAICC.org

CC:

Larry Starfield, Principal Deputy Assistant Administrator, OECA
Jeff Morris, Director, OPPT; chief US Head of Delegation to OECD on Chemicals
Nancy Beck, Acting Assistant Administrator, OSCPP
Louise Wise, Deputy Assistant Administrator, OSCPP
Rick Keigwin, Director, OPP
Ed Messina, Acting Deputy Director, OPP
Daisy Letendre, Smart Sectors Program
Kristinn Sharp, Smart Sectors Program